

XALACOM[®] EYE DROPS

Latanoprost/Timolol (50 micrograms/mL and 5 mg/mL)

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What is in this leaflet

1. What XALACOM is used for
2. How XALACOM works
3. Before you use XALACOM
4. How to use XALACOM
5. While you are using it
6. Side Effects
7. Storage and Disposal of XALACOM
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision
11. Serial Number

What XALACOM is used for

Reduction of intraocular pressure (IOP) in patients with open angle glaucoma and ocular hypertension who are insufficiently responsive to topical beta-blockers.

XALACOM is used to reduce the pressure in your eye if you have conditions known as open angle glaucoma or ocular hypertension. Both these conditions are linked to an increase in the pressure within your eye, eventually affecting your eyesight. Your doctor will usually prescribe you XALACOM when other medicines have not worked adequately.

How XALACOM works

XALACOM contains two medicines: latanoprost and timolol. Latanoprost belongs to a group of medicines known as prostaglandin analogues. Timolol belongs to a group of medicines known as beta-blockers. Latanoprost works by increasing the natural outflow of fluid from the eye into the bloodstream. Timolol works by slowing the formation of fluid in the eye.

Before you use XALACOM

XALACOM can be used in adult men and women (including the elderly), but is not recommended for use if you are less than 18 years of age.

- When you must not use it

Do not use XALACOM:

- if you are allergic (hypersensitive) to either of the medicines in XALACOM (latanoprost or timolol)

or any of the other ingredients of XALACOM (see Section Product Description).

- if you have or have had in the past respiratory problems such as asthma, severe chronic obstructive pulmonary disease (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough).
- if you have serious heart problems or heart rhythm disorders.

Pregnancy and lactation

Do not use XALACOM if you are pregnant unless your doctor considers it necessary. Tell your doctor immediately if you are pregnant, think you are pregnant or are planning to become pregnant.

Do not use XALACOM if you are breast-feeding. XALACOM may get into your milk. Ask your doctor for advice before taking any medicine during breast-feeding.

- Before you start to use it

Talk to your doctor or pharmacist before using XALACOM if you have now or have had in the past:

- Coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, low blood pressure (hypotension)
- Disturbances of heart rate such as slow heart beat (bradycardia)
- Breathing problems, asthma or chronic obstructive pulmonary disease (lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough)
- Poor blood circulation disease (peripheral arterial disease such as Raynaud's disease or Raynaud's syndrome)
- Diabetes, as timolol may mask signs and symptoms of low blood sugar.
- Overactivity of the thyroid gland, as timolol may mask signs and symptoms
- You are about to have any kind of eye surgery (including cataract

surgery) or have had any kind of eye surgery in the past.

- You suffer from eye problems (such as eye pain, eye irritation, eye inflammation or blurred vision).
- You know that you suffer from dry eyes.
- You wear contact lenses. You can still use XALACOM but follow the instructions for contact lens wearers (see Section How to use XALACOM).
- You know that you suffer from angina (particularly a type known as Prinzmetal angina).
- You know that you suffer from severe allergic reactions that would usually require hospital treatment.
- You have suffered or are currently suffering from a viral infection of the eye caused by the herpes simplex virus (HSV).

Tell your doctor before you have an operation that you are using XALACOM as timolol may change effects of some medicines used during anaesthesia.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

XALACOM can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma. Tell your doctor if you are using or intend to use medicines to lower blood pressure, to treat heart conditions or to treat diabetes. In particular, speak to your doctor or pharmacist if you know that you are taking any of the following types of medicine:

- Prostaglandins, prostaglandin analogues or prostaglandin derivatives
- Adrenaline (epinephrine)
- Drugs used to treat high blood pressure, such as oral calcium channel blockers, beta-adrenergic blocking agents, guanethidine, antiarrhythmics, digitalis glycosides

XALACOM® EYE DROPS

Latanoprost/Timolol (50 micrograms/mL and 5 mg/mL)

or parasympathomimetics.

- Quinidine (used to treat heart conditions and some types of malaria)
- Antidepressants, such as fluoxetine and paroxetine
- Timolol
- Clonidine

How to use XALACOM

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The usual dosage for adults (including the elderly) is one drop once a day in the affected eye(s).

- When to use it

Use as directed by your doctor or pharmacist.

Use in children

XALACOM is not recommended for children and adolescents.

- How long to use it

Continue taking XALACOM for as long as your doctor recommends.

Your doctor may want you to have extra checks on your heart and circulation if you use XALACOM.

- If you forget to use it

If one dose is missed, treatment should continue with the next dose as planned. The dose should not exceed one drop in the affected eye(s) daily.

- If you use too much (overdose)

If you put too many drops in your eye you may experience some minor irritation in your eye and your eyes may water and turn red. This should pass but if you are worried contact

your doctor for advice.

If you swallow XALACOM accidentally, you should contact your doctor for advice.

If you swallow a lot of XALACOM you may feel sick, have stomach pains, feel tired, flushed and dizzy and start to sweat.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking XALACOM.

Tell your doctor immediately if you become pregnant while taking this medication.

Contact lens wearers

If you wear contact lens, you should remove them before using XALACOM. After using XALACOM you should wait 15 minutes before putting your contact lenses back in.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give XALACOM to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

XALACOM has minor influence on the ability to drive and use machines. As with other eye drops, when you use XALACOM, your vision may become blurred for a short time. If this happens to you, do not drive or use any tools or machines until your vision becomes clear again.

XALACOM contains a preservative called benzalkonium chloride. This preservative may cause eye irritation or disruption to the surface of the eye. It can be absorbed by contact lenses and is known to discolour soft contact lenses. Therefore, avoid contact with soft contact lenses. See the instructions for contact lens wearers in Section While you are using it.

Side Effects

Like all medicines, XALACOM can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You can usually carry on taking the drops, unless the effects are serious. If you are worried, talk to a doctor or pharmacist. Do not stop using XALACOM without speaking to your doctor.

The most important side-effect is the possibility of a gradual, permanent change in your eye colour.

It is also possible that XALACOM might cause serious changes in the way your heart works. If you notice changes in your heart rate or heart function, you should speak to a doctor and tell them you have been using XALACOM.

The following are known side effects of using XALACOM:

Very common (may affect more than 1 in 10 people):

- A gradual change in your eye colour by increasing the amount of brown pigment in the coloured part of the eye known as the iris. This effect is known as iris hyperpigmentation. The effect is predominant if you have mixed-colour eyes (blue-brown, grey-brown, yellow-brown or green-brown). Any changes in your eye colour may take years to develop. The colour change may be permanent and may be more noticeable if you use XALACOM in only one eye. There appears to be no problems

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associated with the change in eye colour. The eye colour change does not continue after XALACOM treatment is stopped.

Common (may affect up to 1 in 100 people):

- Eye irritation (a feeling of burning, grittiness, itching, stinging or the sensation of a foreign body in the eye) and eye pain.

Other side effects

Although not seen with XALACOM, the following additional side effects have been seen with the medicines in XALACOM (latanoprost and timolol) and therefore might occur when you use XALACOM:

Infections and Infestations:

- Developing a viral infection of the eye caused by the herpes simplex virus (HSV).

Nervous System Disorders:

- Dizziness, tingling or numbness in the skin, changes in blood flow to the brain, worsening of symptoms of myasthenia gravis (if you already suffer from this condition), sudden fainting or feeling you may faint (syncope), headache.

Eye Disorders:

- Changes to the eyelashes and fine hairs around the eye (increased number, length, thickness and darkening), changes to the direction of eyelash growth, red watery eyes affecting vision (punctate keratitis), swelling around the eye, swelling of the coloured part of the eye (iritis/uveitis), swelling at the back of the eye (macular oedema), inflammation/irritation of the surface of the eye (keratitis), dry eyes, visual changes/disturbances, double vision, drooping of the upper eyelid, injury to the lining of the back of the eye (a condition known as retinal detachment, but only seen when used following some kinds of eye surgery), swelling of the eyelid, skin reactions on eyelid, swelling of the cornea, discomfort to the eyes due to light exposure

(photophobia), rashes on the mucous membrane of the eye (pseudopemphigoid of the ocular conjunctiva), fluid filled cyst with the coloured part of the eye (iris cyst), appearance of calcium on the central cornea.

Heart (Cardiac) Disorders:

- Worsening of angina, awareness of heart rhythm (palpitations), changes in heart rhythm, slowing of the heart, heart failure (cardiac arrest, heart block or congestive heart failure).

Breathing (Respiratory) Disorders:

- Asthma, worsening of asthma, shortness of breath, sudden difficulty to breathe (bronchospasm), cough.

Skin Disorders:

- Darkening of the skin around the eyes, hair loss/baldness (alopecia), itchy rash or worsening of itchy skin conditions.

Muscle and Skeletal Disorders:

- Joint pain, muscle pain.

General Disorders:

- Chest pain, fatigue.

Immune System Disorders:

- Symptoms of allergic reaction (swelling and redness of the skin and rash).

Psychiatric Disorders:

- Depression, memory loss, inability to sleep, nightmares and hallucinations (imaginary perceptions like sensory experiences that appear real but are created by person's own mind).

Ear Disorders:

- Whistling/ringing in the ears (tinnitus).

Blood flow (Vascular) Disorders:

- Low blood pressure, discolouration/coldness of the fingers and toes (Raynaud's phenomenon) and coldness of the hands and feet.

Digestive System (Gastrointestinal) Disorder:

- Feeling sick (nausea), diarrhoea, dyspepsia, dry mouth, vomiting.

Reproductive System and Breast Disorders:

- Sexual dysfunction, decreased libido.

If you get any side effects talk to your doctor. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of XALACOM

- Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated after EXP on the carton and bottle label. The expiry date refers to the last day of that month.

The shelf life before first opening of the container is 3 years. Store in a refrigerator (2°C - 8°C). The shelf life after opening of the container is 4 weeks.

After first opening of the bottle: Do not store above 25°C.

Keep the bottle in the outer carton in order to protect from light.

Use within 4 weeks.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

Product Description

- What it looks like

XALACOM Eye Drops is a clear and colourless solution.

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- Ingredients

- *Active ingredients*

The active substances are latanoprost
50 micrograms/mL and timolol (as
timolol maleate) 5 mg/mL

- *Inactive ingredients*

The other ingredients are:

Sodium chloride
Benzalkonium chloride
Sodium dihydrogen phosphate
monohydrate
Disodium phosphate
Hydrochloric acid solution (for
adjustment to pH 6.0)
Sodium hydroxide solution (for
adjustment to pH 6.0)
Water for injections

- MAL number

XALACOM
Eye Drops MAL20032154ACRZ

Manufacturer

Pfizer Manufacturing
Belgium NV, Puurs-Sint-Amands,
Belgium

Product Registration Holder

Viatrix Sdn Bhd
15-03 & 15-04, Level 15, Imazium,
No. 8, Jalan SS 21/37,
Damansara Uptown,
47400 Petaling Jaya,
Selangor, Malaysia.

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